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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,234	09/25/2000	Pascal Vannuffel	VANM145.001A	9668

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EXAMINER	
MYERS, CARLA J	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,234	VANNUFFEL ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,7-10,13,14,33 and 43-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 5, 7-10, 13, 14, 33 and 43-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. This action is in response to the amendment filed January 3, 2003. Claims 6, 11, 15-23, 31, 32 and 34-42 have been cancelled. Claims 43-50 were newly added. Accordingly, claims 1, 2, 5, 7-10, 13, 14, 33 and 43-50 are pending. Applicants amendments and arguments have been fully considered but are not persuasive to overcome all grounds of rejection. This action is made final.

2. This application contains claims that include subject matter drawn to an invention nonelected with traverse in Paper No. 18, i.e. SEQ ID NO: 18-40, 42, 44, 46, 48, 50 and 52. Again, this is not an election of species, but rather a restriction requirement. A complete reply to the final rejection must include cancellation of the nonelected subject matter or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

3. The specification is objected to because the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR §1.821(d).

In the response of January 3, 2003, Applicants state that the specification has been amended to include SEQ ID NO's. However, the specification has not been amended to include SEQ ID NO's next to each referenced sequence. FOR EXAMPLE, the specification refers to Figure 3, which consists of a sequence. However, in the description of Figure 3 and next to each reference to Figure 3, the specification does not include the appropriate SEQ ID NO.

4. Claim 7-10, 13, 14, 33 and newly added claims 43-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-10, 13, 14, 33, and newly added claims 43-50 are indefinite because it is not clear as to whether the claims are drawn to 2 or more oligonucleotides wherein each oligonucleotide is distinct from the others or whether the claims are drawn to multiple copies of the same oligonucleotide. Furthermore, since the claims recite two or more oligonucleotides in which one of the oligonucleotides may comprise a sequence having 60% identity with SEQ ID NO: 1 **and/or** one oligonucleotide may comprise a sequence having at least 60% identity with SEQ ID NO: 1, 46, 48, 50 or 52, in claims 8-10 it is unclear as to whether the oligonucleotides must share 70-90% identity with stated sequences or with only one of the stated sequences.

RESPONSE TO ARGUMENTS:

In the response filed January 3, 2003, Applicants state that the claims have been amended to delete "and/or". It is stated that from the two or more oligonucleotides at least one oligo is homologous to SEQ ID NO: 1 or one oligo is homologous to a sequence selected from SEQ ID NO: 1 and 29-37. However, the rejection is maintained because it remains unclear as to whether the claims include 2 copies of the same oligonucleotide (e.g., 2 copies of an oligonucleotide consisting of SEQ ID NO: 1) or whether the claim intends to include 2 different oligonucleotides (e.g.. wherein one oligonucleotide consists of SEQ ID NO: 1 and the second oligonucleotide consists of a 25 mer fragment of SEQ ID NO: 1).

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAMS:

Claims 47-50 are indefinite over the recitation of "A diagnostic kit according to claim 14" because this phrase lacks proper antecedent basis. While claim 14 refers to a diagnostic device, it does not refer to a diagnostic kit.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 7-10, 13 and 14 and newly added claims 43-45 and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Unal (Journal of Clinical Microbiology (1992) 30:1685-1691; cited in the IDS of Paper No. 6).

Unal et al (page 1686) teaches primers for amplifying the femA gene of Staphylococcus. The primers include: a) a 23-mer forward primer which is 100% homologous to nucleotides 765-786 of SEQ ID NO: 1; and b) a 19-mer reverse primer which is 95% complementary to nucleotides 1735-1753 of SEQ ID NO: 1. Accordingly, Unal teaches oligonucleotides comprising 15 to 350 or 17 to 250 nucleotides of SEQ ID NO: 1. The primers of Unal are also considered to be a diagnostic device for identifying Staphylococci species. Furthermore, Unal teaches methods for detecting Staphylococcus wherein the methods comprise amplifying sample nucleic acids using said primers, separating the amplification products by gel electrophoresis and detecting the amplification products and the size of the amplification products as indicative of the

presence of Staphylococcus (see page 1688). Unal also teaches that the femA gene can be detected using a hybridization probe (pages 1688-1689).

RESPONSE TO ARGUMENTS:

In the response filed January 3, 2003, Applicants traverse this rejection by stating that the claims have been amended to recite that the oligonucleotide comprises from about 25 to 350, about 25 to 250 or about 25 to 45 base pairs of SEQ ID NO: 1. Applicants state that Unal does not teach oligonucleotides in these size ranges. This argument is not convincing because the claims recite the language "about 15..." and thereby include oligonucleotides of a length less than 25. Thus, the claims include the oligonucleotides of Unal which are 23 and 19 nucleotides in length. Applicants have not defined the term "about" and have not established any criticality with respect to the length of the oligonucleotide being 25 or more nucleotides. In fact, the specification indicates that the oligonucleotides are preferably about 15 or more nucleotides. For example, at pages 7 to 8 of the specification, it is stated that the oligonucleotides have "between 15 and 350 base pairs, preferably between 17 and 250 base pairs" and preferably that the oligonucleotides are primers "having between 15 and 45 base pairs, more preferably between 17 and 25 base pairs". There are no teachings in the specification which would suggest that "about 25 nucleotides" is intended to exclude 23 or 19 nucleotides. Accordingly, the claims as written read on the oligonucleotides of Unal having a length of 23 or 19 nucleotides.

With respect to claims 13 and 14, Applicants state that the claims are limited to methods of identifying various Staphylococci strains and that Unal does not teach such a method. It is

stated that Unal teaches only methods for detecting the S. aureus and does not teach detecting other Staphylococci strains. This argument has been fully considered but is not persuasive because the claims do not require the simultaneous detection of 2 different Staphylococci species. Rather the claims are inclusive of detecting a single Staphylococcus species, such as S. aureus. With respect to the claims drawn to diagnostic devices, these claims also do not require detecting multiple, distinct Staphylococci species. Additionally, in claims to products, such as the "diagnostic device", the intended use of the product does not carry weight with respect to the determination of novelty of the product. As stated in MPEP 211.02, "When the claim is directed to a product, the preamble is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property in the old composition. *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 480-481". The MPEP (2112) further states that "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable". Accordingly, the claimed diagnostic device is anticipated by the oligonucleotides of Unal.

6. Claims 1, 2, 5, 7-10, 13 and 14 and newly added claims 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Alborn et al (EP 0625575 A2; cited in the IDS of Paper No. 6).

Alborn et al (pages 4-6) teaches a Staphylococcus epidermidis femA nucleotide sequence which comprises sequences of 15-350, 17-250 or 17-25 nucleotides having 100% identity with instant SEQ ID NO: 1. With respect to claims 7-10, the claims have been interpreted as including multiple copies of the same oligonucleotide and Alborn teaches compositions comprising multiple

copies of the femA nucleic acids. The nucleic acid of Alborn is also considered to be a diagnostic device for identifying Staphylococci species.

RESPONSE TO ARGUMENTS:

In the response filed January 3, 2003, Applicants traverse this rejection by stating that the claims have been amended to recite that the oligonucleotide comprises from about 25 to 350, about 25 to 250 or about 25 to 45 base pairs of SEQ ID NO: 1. Applicants state that Alborn does not teach oligonucleotides in these size ranges. However, the claims are not limited to oligonucleotides which are of a length of 25 to 350, 25 to 250 or 25 to 45 nucleotides. Rather, the claims include oligonucleotides **comprising** fragments of SEQ ID NO: 1 wherein the fragments are of a length of 25 to 350, 25 to 250 or 25 to 45 nucleotides. Accordingly, the claimed oligonucleotides are not limited to particular length and may be of any length. The nucleic acids of Alborn contains fragments of SEQ ID NO: 1 that are of lengths of, for example, 179 bp (nucleotides 17-195 of SEQ ID NO: 1). and 1067 nucleotides (nucleotides 197-1263 of SEQ ID NO: 1) and thereby anticipate the claimed nucleic acids. Applicants further traverse the rejection by arguing that Alborn teaches only methods for detecting the S. epidermis and does not teach detecting other Staphylococci strains. This argument has been fully considered but is not persuasive because the claims do not require the simultaneous detection of 2 different Staphylococci species. Rather the claims are inclusive of detecting a single Staphylococcus species, such as S. epidermis. With respect to the claims drawn to diagnostic devices, these claims also do not require detecting multiple, distinct Staphylococci species. Additionally, in claims to

products, such as the "diagnostic device", the intended use of the product does not carry weight with respect to the determination of novelty of the product, as discussed in detail above.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Unal in view of the Stratagene Catalog.

Unal et al (page 1686) teaches primers for amplifying the femA gene of Staphylococcus. The primers include: a) a 23-mer forward primer which is 100% homologous to nucleotides 765-786 of SEQ ID NO: 1; and b) a 19-mer reverse primer which is 95% complementary to nucleotides 1735-1753 of SEQ ID NO: 1. Accordingly, Unal teaches oligonucleotides

comprising 15 to 350 or 17 to 250 nucleotides of SEQ ID NO: 1. The primers of Unal are also considered to be a diagnostic device for identifying Staphylococci species. Furthermore, Unal teaches methods for detecting Staphylococcus wherein the methods comprise amplifying sample nucleic acids using said primers, separating the amplification products by gel electrophoresis and detecting the amplification products and the size of the amplification products as indicative of the presence of Staphylococcus (see page 1688). Unal also teaches that the femA gene can be detected using a hybridization probe (pages 1688-1689). While Unal teaches the reagents for the detection of amplification products, Unal does not teach a "diagnostic device" or kit comprising the primers and the reagents necessary for detection of amplification products.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatibility of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers and reagents for detecting amplification products of Unal in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to detect Staphylococcus femA nucleic acids.

RESPONSE TO ARGUMENTS:

In the response of January 3, 2003, Applicants traverse this rejection by stating the primers of Unal do not allow for the detection of coagulase-negative Staphylococcus. Applicants conclude that it would therefore not be obvious to package the oligonucleotides of Unal in a kit for identifying various types of known and unknown Staphylococcus species. This argument is not persuasive because the claims do not require any oligonucleotides that specifically detect multiple Staphylococci species. Further the intended use of a kit does not carry weight with respect to the obviousness of the kit. The claims do not recite any components which would require that the kit necessarily contain reagents that detect multiple species of Staphylococci.

8. **THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAMS:**

Claims 1, 2, 5, 7-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide basis for the specific concept of an oligonucleotide comprising about 25 to 350 base pairs, about 25 to 250 base pairs or about 25 to 45 base pairs of SEQ ID NO: 1. The specification (pages 7 to 8) as originally filed provides basis for the concepts of oligonucleotides having "between 15 and 350 base pairs, preferably between 17 and 250 base pairs" and for oligonucleotides that are primers "having between 15 and 45 base pairs, more preferably between 17 and 25 base pairs". The preferred embodiment in the

specification sets the lower limit for the oligonucleotides at about 15 nucleotides and the specification teaches that the oligonucleotides may be of a longer length of up to 350, 250 or 45 nucleotides. However, the specification does not provide basis for the specific embodiment that the oligonucleotide is at least about 25 and does not provide support for the specific genus of oligonucleotides that comprise about 25 to 350 base pairs, about 25 to 250 base pairs or about 25 to 45 base pairs of SEQ ID NO: 1

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Pauline Farrier whose telephone number is (703) 305-3550.

Carla Myers

July 1, 2003

CARLA J. MYERS
PRIMARY EXAMINER